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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/768,965

02/02/2004

Yuji Nakajima

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EXAMINER

ROONEY, NORA MAUREEN

ART UNIT

PAPER NUMBER

1644

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

12/19/2006

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/768,965

Applicant(s)

NAKAJIMA ET AL.

Examiner

Nora M. Rooney

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 9-30 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 03/24/2004.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

1. Claims 1-30 are pending.
2. Applicant's election without traverse of Group I, claims 1-8, is acknowledged.
3. Claims 9-30 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.
4. Claims 1-8 are under examination as they read on an allergen inactivating method.
5. Applicant's IDS, filed 03/24/2004, is acknowledged. The AF and AG references were crossed out because they are in Japanese.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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7. Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Applicant is not in possession of: **An allergen** inactivating method by maintaining **the allergens** under a condition in which any one selected from the group consisting of heat, an alkali, an acid and an enzyme exists; the allergen inactivating method according to claim 1, wherein the enzyme is a protease; the allergen inactivating method according to claim 1, by maintaining **the allergens** under a condition in which the enzyme and a denaturing agent exist; or the allergen inactivating method according to claim 3, wherein the denaturing agent is any one of a surfactant, urea and a salt.

Neither the exemplary embodiments nor the specification's general method appears to describe structural features, in structural terms, that are common to the genus. That is, the specification provides neither a representative number of species (allergens) to describe the claimed genus, nor does it provide a description of structural features that are common to species (allergens). As discussed above, the specification provides no structural description of allergens other than ones specifically exemplified; in essence, the specification simply directs those skilled in the art to go figure out for

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themselves what the claimed **allergen** looks like. The specification's disclosure is inadequate to describe the claimed genus of **an allergen inactivating method**.

Adequate written description requires more than a mere statement that it is part of the invention. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC1993). The Guidelines for the Examination of Patent Application Under the 35 U.S.C.112, ¶ 1 "Written Description" Requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 20001, see especially page 1106 3<sup>rd</sup> column).

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.). Consequently,

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Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Applicant is directed to the final Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

8. Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an allergen inactivating method for the Cryj-2 and Cryj-1 cedar antigens and dust mite extract-Df allergens by maintaining the cedar antigen and dust mites allergens under a condition in which any one selected from the group consisting of heat at 80°C, sodium hydroxide, hydrochloric acid and pfu or papain enzymes exists, does not reasonably provide enablement for **An allergen** inactivating method by maintaining **the allergens** under a condition in which any one selected from the group consisting of **heat, an alkali, an acid and an enzyme exists**; the allergen inactivating method according to claims 1 and 5, wherein the enzyme is a protease in claims 2 and 6; the allergen inactivating method according to claim 1, by maintaining **the allergens** under a condition in which the enzyme and a **denaturing agent** exist in claims 3 and 7;, wherein the denaturing agent is any one of a surfactant, urea and a salt in claims 4 and 8. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the lack of sufficient working examples, the unpredictability in the art and the amount of experimentation required to enable one of skill in the art to practice the claimed invention.

The specification fails to provide sufficient enablement for a person of skill in the art to make and use an inactivating method for any allergen because the specification and claims offer no guidance as to what particular substance, other than dust mite extract and Cyj-1 and Cyj-2 cedar allergens, that are inactivated by the claimed method. A myriad of allergens are encompassed by the claims. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of allergens broadly encompassed by the claims and the claims broadly encompass a significant number of inoperative species. For example, in Maleki et al. it is demonstrated that denaturation of peanut proteins by roasting the peanuts increases binding to serum IgE from allergic individuals at approximately 90 fold higher levels than uncooked peanuts. (PTO-892, Page 1, Reference U, page 767 first paragraph of discussion) The claims encompass any allergen from any food or substance that is associated with any allergic disease and symptoms and a variety of inactivation methods. However, there are many allergen/inactivation method

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combinations that do not work, as is evidenced by Maleki et al. There is great unpredictability in the art and an undue amount of experimentation is required to practice the claimed invention.

Reasonable correlation must exist between the scope of the claims and scope of the enablement set forth. In view on the quantity of experimentation necessary the limited working examples, the nature of the invention, the state of the prior art, the unpredictability of the art and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

***Claim Rejections - 35 USC § 102***

14 The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Finley et al. (PTO-892, Page 1, Reference V) as evidenced by Figueredo et al. (PTO-892, Page 1, Reference W).

Finley et al. teaches using a protease (papain) to remove the chill haze from beer that has been fermented (37°C) (entire document, line 1 in particular). As evidenced by



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Figueredo et al., beer can be an allergen and it is made from malt that is obtained from germinated and heated or roasted barley (heat applied) (entire document, abstract, lines 1-5 on page 630). Many types of beer inherently contain salt as an ingredient or are drunk with salty foods. The beer allergens have inherently been inactivated according to the claimed invention.

The reference teachings anticipate the claimed invention.

16. Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Burks et al. (PTO-892, Page 1, Reference X)

Burks et al. teaches using a protease and heat to denature peanut and soybean allergens for reduced IgE binding. (In particular, Abstract). Peanuts and soybeans are common allergens and they inherently contain salt. The peanut and soybean allergens are inherently inactivated according to the claimed invention.

The reference teachings anticipate the claimed invention

17. Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Kang et al. U.S. Patent Number 3,818,106 (PTO-892, Page 1, Reference A).

Kang et al. teaches using the protease bromelain to tenderize meat that is later cooked (In particular, Column 13-14, Example VIII). Salts of EDTA were added as a chelating agent (In particular, column 7, lines 20-27). Meat allergies to chicken, beef

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and pork have been documented as evidenced by Cahen et al. (PTO-892, Page 2, Reference U, abstract) and Mamikoglu et al. (PTO-892, Page 2, Reference V, abstract). The meat allergens are inherently inactivated according to the claimed invention.

The reference teachings anticipate the claimed invention

18. Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Jost et al. U.S. Patent Number 5,039,532 (PTO-892, Page 1, Reference B).

Jost et al. teach a method of using a protease (Porcine trypsin) to hydrolyze whey powder containing allergens (In particular, column 2, lines 14-29). The method includes a heating step of 70, 80 or 90 degrees and the results were shown by SDS page ( In particular, column 2, line 66- column 3, line 10). The whey protein allergens were inherently inactivated according to the claimed invention.

The reference teachings anticipate the claimed invention

19. No claim is allowed.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nora M. Rooney whose telephone number is (571) 272-9937. The examiner can normally be reached Monday through Friday from 8:30 am to 5:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina

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Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

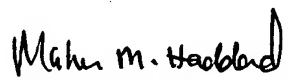
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November 9, 2006

Nora M. Rooney, M.S., J.D.

Patent Examiner

Technology Center 1600

  
MAHER M. HADDAD  
PRIMARY EXAMINER